APR 2 6 2012

BIOMET SPINE

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date:	April 25, 2012
Applicant/Sponsor:	Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Margaret F. Crowe Phone: 973-299-9300, ext. 2260 Fax: 973-257-0232
Trade name:	Solitaire®-C Cervical Spacer System
Common Name:	Cervical interbody fusion device with integrated fixation
Classification Name (Product Code):	Intervertebral Body Fusion Device (OVE)
Device Panel - Regulation No.:	Orthopedics - 21 CFR 888.3080

Device Description:

The purpose of this submission is to gain market clearance for the Solitaire-C Cervical Spacer System. The Solitaire®-C Cervical Spacer System consists of spacers and bone screws for stand-alone cervical intervertebral body fusion. The Solitaire®-C spacer will be available in a variety of sizes, angles and footprints.
This cervical spacer has a PEEK main body (PEEK-Optima LT1 per ASTM F-2026) with a titanium faceplate and band (Ti-6Al-4V ELI alloy per ASTM F-136), and tantalum markers (unalloyed tantalum per ASTM F-560). This device accepts titanium bone screws that are available in two diameters and multiple lengths.

Indications for Use:

The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire®-C Cervical Spacer is to be used with autograft and implanted via an anterior approach. The Solitaire-C spacer must be implanted with the Solitaire-C titanium screws that are part of the system. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Summary of Technologies:

The technological characteristics (material, design and sizing) of the Solitaire-C Cervical Spacer System is the same as, or similar to, the predicate devices. Examples of predicate devices include:

- Solitaire PEEK Anterior Spinal System (Biomet Spine - K081395, K093629)
- Coalition Spacer (Globus Medical – K083389)
- AVS-C Spacer (Stryker Spine – K102606)
- Synthes Zero-P Cervical Spacer (Synthes Spine – K072981, K093762)
- C-Thru Spacer System (Biomet Spine – K092336)

Performance Data

Mechanical testing recommended in the special controls guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was conducted. The testing conducted, along with the ASTM standard, are listed below:

1) Static Axial Compression (ASTM F-2077)
2) Dynamic Axial Compression (ASTM F-2077)
3) Static Compression-Shear (ASTM F-2077)
4) Dynamic Compression-Shear (ASTM F-2077)
5) Static Torsion (ASTM F-2077)
6) Dynamic Torsion (ASTM F-2077)
7) Subsidence (ASTM F-2267 and ASTM F-2077)
8) Expulsion (ASTM Draft F-04.25.02.02)

Additional mechanical testing was conducted to evaluate screw back out, screw push through, and interconnection testing between the spacer body and the faceplate. Wear debris analysis was also presented.

Mechanical testing shows that the mechanical strength of the subject device is sufficient for its intended use.

Substantial Equivalence:

The Solitaire-C Cervical Spacer System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. The predicates listed above are distributed for similar indications, and/or have similar design features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 26 2012

Biomet Spine
% Ms. Margaret F. Crowe
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K113796
Trade/Device Name: Solitaire®-C Cervical Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: OVE
Dated: March 15, 2012
Received: March 16, 2012

Dear Ms. Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

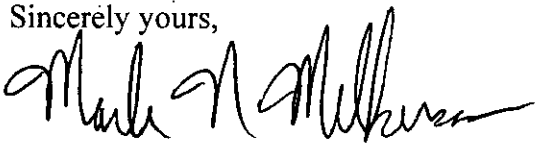
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113796

Device Name: Solitaire®-C Cervical Spacer System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113796